REMARKS

In response to the final Office Action of April 1, 2004, Applicants file this Amendment with a Request for Continued Examination. In the Office Action, the Examiner rejected the pending claims under 35 U.S.C § 112, first paragraph, as failing to comply with the written description requirement. The Examiner alleges that the disclosure does not disclose "positioning a passive device such that, at least **during systole**, a portion of the device contacts and passively alters a geometry of heart structure **other than** leaflets, chordae, papillary muscles, and an annulus associated with the *in situ* mitral valve **so as to draw together leaflets of the *in situ* valve** to promote closure of the *in situ* valve." (Page 2, emphasis in original.) The Examiner further alleges that "one would expect that the alteration of the 'other' heart structure occurs **during diastole only**, since otherwise the passive device would interfere with the normal post-systolic dilation of the heart cavities." (Page 2, emphasis in original.)

Though Applicants do not necessarily agree with the Examiner's rejection and assertions, Applicants have amended independent claim 83 to more clearly define the claimed invention. Claim 83 recites a method of treating an in situ mitral valve. The method includes positioning a passive device with respect to a heart such that, throughout the cardiac cycle, a portion of the device contacts and passively alters a geometry of heart structure other than leaflets, chordae, papillary muscles, and an annulus associated with the in situ mitral valve. The passive device draws together leaflets of the in situ valve to promote closure of the in situ valve.

The original disclosure teaches "positioning a passive device with respect to a heart such that, throughout the cardiac cycle, a portion of the device contacts and passively alters a geometry of heart structure other than leaflets, chordae, papillary

muscles, and an annulus associated with the in situ mitral valve." For example, Figure 9 shows a valve repair device 220 that includes a tension member 225 anchored to the heart wall at pads 227. The specification states that "[t]ension member 225 can be used to further alter the geometry of the left ventricle 10 in a manner disclosed in U.S. Patent Application Serial No. 08/993,456 . . . incorporated herein by reference." (See specification, page 8, line 25 to page 9, line 3.) That incorporated application, which issued as U.S. Patent No. 5,961,440, further clarifies that the tension member, *throughout the cardiac cycle*, contacts and passively alters a geometry of heart structure other the specified structure associated with the mitral valve. For example, the '440 patent, in the Summary of the Invention section, describes the device as "reduc[ing] wall tension *during diastole and systole*." ('440 patent, col. 2, lines 54-55.) To reduce heart wall tension during diastole and systole, the geometry of the heart wall is necessarily altered during both diastole and systole. The relationship between altering heart wall geometry and reducing heart wall tension is explained in the '440 patent with respect to its Figures 36-40. (See '440 patent, col. 10, line 16 to col. 11, line 7.) Thus, contrary to the assertions in the Office Action, the as-filed disclosure fully supports that a passive device, e.g., the tension member, alters geometry of the heart structure throughout the cardiac cycle, i.e. during diastole and systole.

The original disclosure also teaches that "the passive device draws together leaflets of the in situ valve to promote closure of the in situ valve." For example, again referring to Figure 9, device 220 also includes tension members 224 that extend from a basal anchor 222 to secondary anchor points at pads 227. As mentioned in the specification, this is similar to that shown in Figure 7 (page 8, lines 15-19), which is a

view of device 20 of Figure 4 (page 8, lines 1-2). As also explained in the specification, the device 20 of Figure 4, among other things, draws papillary muscles toward the mitral valve and valve function is improved. (Page 6, lines 18-25.) Drawing papillary muscles toward the valve will provide stress relief on the valve leaflets and promote closure of the valve. (See, e.g., specification at page 7, lines 20-26.) Thus, the as-filed specification fully supports the claimed recitation of "the passive device draw[ing] together leaflets of the in situ valve to promote closure of the in situ valve."

On page 2 of the Office Action, the Examiner refers to U.S. Patent No. 5,800,528 to Lederman et al. ("Lederman"), without making a rejection. The Examiner asserts that "although the present invention is said to improve the functioning of the mitral valve during systole, the same is likely true of certain prior art devices (e.g., US 5,800,528) which passively reduce ventricular dilatation."

To the contrary, Lederman expressly teaches that its invention is limited to affecting the heart during only diastole. Lederman summarizes its invention as follows: "Broadly speaking in the present invention a completely passive girdle is wrapped around the ventricle or the entire heart muscle, and sized so that it constrains the dilatation during diastole and does not effect the action of the ventricle during systole." (Col. 3, lines 4-8.) Lederman describes its embodiments consistent with that teaching. For example, with reference to Figure 4, Lederman teaches that "[t]he purpose of this net is to limit the maximum diastolic dimension of the heart, while offering no resistance to systolic ejection. . . . The design of FIG. 4 presents no systolic load to the contracting heart." (Col. 5, lines 20-30.) Thus, Lederman does not disclose or suggest "positioning a passive device with respect to a heart such that, throughout the cardiac cycle, a

portion of the device contacts and passively alters a geometry of heart structure other than leaflets, chordae, papillary muscles, and an annulus associated with the in situ mitral valve."

Moreover, Lederman also does not disclose or suggest a "passive device [that] draws together leaflets of the in situ valve to promote closure of the in situ valve." Lederman discloses a device that allegedly decreases dilatation of the ventricle over time. Lederman has no teaching or suggestion that its devices have any effect on the mitral valve. Lederman in fact contains no discussion of the mitral valve within its disclosure. For all these reasons, Lederman does not anticipate or render obvious the claimed invention.

In view of these remarks, this claimed invention fully complies with Section 112 and is neither anticipated nor rendered obvious in view of the prior art references cited against this application. Applicants request the entry of this Amendment, the Examiner's reconsideration of the application, and the timely allowance of the pending claims.

The Office Action contains characterizations of the claims and the related art with which Applicants do not necessarily agree. Unless expressly noted otherwise, Applicants decline to subscribe to any statement or characterization in the Office Action.

In discussing the specification, claims, and drawings in this Amendment, Applicants are in no way intending to limit the scope of the claims to any exemplary embodiments described in the specification or shown in the drawings. Rather, Applicants are entitled to have the claims interpreted broadly, to the maximum extent permitted by statute, regulation, and applicable case law.

Please grant any extensions of time required to enter this Amendment and charge any additional required fees to our Deposit Account No. 06-0916.

Respectfully submitted,

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